

Food and Drug Administration, HHS

§ 558.450

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in growing-finishing swine.

[40 FR 13959, Mar. 27, 1975, as amended at 44 FR 40283, July 10, 1979; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 66 FR 47963, Sept. 17, 2001]

§ 558.450 Oxytetracycline.

(a) *Approvals.* Type A medicated articles:

(1) 10, 20, 30, 50, 100, and 200 grams per pound to No. 066104 in § 510.600(c) of this chapter.

(2) 50, 100, and 200 grams per pound to No. 048164 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) In accordance with § 558.5 labeling shall bear the statement: “FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.”

(2) The articles in paragraph (a)(1) of this section contain an amount of mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(3) 50-, 100-, and 200-gram per pound articles in paragraph (a)(2) of this section contain oxytetracycline dihydrate expressed in terms of an equivalent amount of oxytetracycline hydrochloride. Another 100-gram per pound article in paragraph (a)(2) of this section contains oxytetracycline hydrochloride.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use—(1) Chickens—*

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 grams per ton (g/ton).	Chickens: For increased rate of weight gain and improved feed efficiency..	Feed continuously; do not feed to chickens producing eggs for human consumption..	066104, 048164
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by <i>Mycoplasma synoviae</i> and control of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 days (d); do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter..	066104, 048164
(iii) 400 g/ton	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter..	066104, 048164
(iv) 500 g/ton	Chickens: For reduction of mortality due to air sacculitis (air sac infection) caused by <i>E. coli</i> susceptible to oxytetracycline..	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds, withdraw 3 d before slaughter..	066104, 048164

(2) Turkeys—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton ...	Growing turkeys: For increased rate of weight gain and improved feed efficiency..	Feed continuously; do not feed to turkeys producing eggs for human consumption..	066104, 048164
(ii) 100 g/ton	Turkeys: For control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	066104, 048164

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(iii) 200 g/ton	Turkeys: For control of infectious synovitis caused by <i>M. synoviae</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 066104 withdraw 5 d before slaughter; for No. 048164 zero-day withdrawal time; do not feed to turkeys producing eggs for human consumption..	066104, 048164
(iv) 25 milligrams/ pound (mg/lb) of body weight daily.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 066104 withdraw 5 d before slaughter; for No. 048164 zero-day withdrawal time; do not feed to turkeys producing eggs for human consumption..	066104, 048164

(3) *Swine*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton ...	Swine: For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 048164
(ii) 10 mg/lb of body weight daily.	1. Swine: For treatment of bacterial enteritis caused by <i>E. coli</i> and <i>Salmonella choleraesuis</i> susceptible to oxytetracycline and treatment of bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d.	066104, 048164
.....	2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to oxytetracycline..	Feed continuously for 14 d.	066104, 048164

(4) *Cattle*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.05 to 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency..	Feed continuously in milk replacer or starter feed..	066104, 048164
(ii) 10 mg/lb of body weight daily.	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia (shipping fever complex) caused by <i>P. multocida</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 048164, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal time..	066104, 048164

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.....	2. Calves: For treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d in milk replacer or starter feed; for No. 048164, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal time..	066104, 048164
(iii) 25 mg/head/day.	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 048164
(iv) 75 mg/head/day.	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses..	Feed continuously.	066104, 048164
(v) 0.5 to 2.0 g/head/day.	Cattle: For prevention and treatment of the early stages of shipping fever complex..	Feed 3 to 5 d before and after arrival in feedlots..	066104, 048164

(5) *Minor species—*

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 20 g/ton ...	Sheep: For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 048164
(ii) 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter..	066104, 048164
(iii) 200 mg/colony	Honey bees: For control of American foulbrood caused by <i>Paenibacillus larvae</i> and European foulbrood caused by <i>Streptococcus pluton</i> susceptible to oxytetracycline..	Remove at least 6 weeks prior to main honey flow..	066104, 048164
(iv) 250 mg/kilogram of fish/day (11.35 g/100 lb of fish/day).	Pacific salmon: For marking of skeletal tissue..	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days; fish not to be liberated for at least 7 d following the last administration of medicated feed..	066104

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(v) 2.5 to 3.75 g/100 lb of fish/day.	1. Salmonids: For control of ulcer disease caused by <i>Hemophilus piscium</i> , furunculosis caused by <i>Aeromonas salmonicida</i> , bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> , and pseudomonas disease..	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed..	066104
.....	2. Catfish: For control of bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> and pseudomonas disease..	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F)..	066104
(vi) 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: For control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> ..	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed..	066104
.....	2. Freshwater-reared <i>Oncorhynchus mykiss</i> : For control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> ..	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed..	066104
(vii) 1 g/lb of medicated feed.	Lobsters: For control of gaffkemia caused by <i>Aerococcus viridans</i> ..	Administer as sole ration for 5 consecutive days; withdraw medicated feed 30 d before harvesting lobsters..	066104

(6) Oxytetracycline may be used in accordance with the provisions of this section in the combinations as follows:

- (i) Carbadox as in § 558.115.
- (ii) Lasalocid as in § 558.311.
- (iii) Melengestrol acetate as in § 558.342.
- (iv) Robenidine hydrochloride as in § 558.515.
- (v) Salinomycin as in § 558.550.

[61 FR 51590, Oct. 3, 1996, as amended at 63 FR 41192, Aug. 3, 1998; 66 FR 32740, June 18, 2001; 66 FR 45167, Aug. 28, 2001; 66 FR 47963, Sept. 17, 2001; 67 FR 51081, Aug. 7, 2002; 69 FR 28821, May 19, 2004; 69 FR 51173, Aug. 18, 2004; 69 FR 62407, Oct. 26, 2004; 71 FR 27958, May 15, 2006; 71 FR 44887, Aug. 8, 2006; 71 FR 53006, Sept. 8, 2006; 72 FR 70774, Dec. 13, 2007; 73 FR 45875, Aug. 7, 2008]

§ 558.455 Oxytetracycline and neomycin.

(a) *Specifications.* Type A medicated articles containing oxytetracycline equivalent to 50 grams per pound (g/lb) oxytetracycline hydrochloride and 50 g/lb neomycin sulfate or oxytetracycline equivalent to 100 g/lb oxytetracycline hydrochloride and 100 g/lb neomycin sulfate.

(b) *Sponsors.* See Nos. 048164 and 066104 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.430 and 556.500 of this chapter.

(d) *Special considerations.* Cattle feeds shall bear the following warning statement: “Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues.”

(e) *Indications for use—(1) Chickens.* It is used in feed as follows: